



PATENT

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B. Webb
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(NE)

Attorney Docket No.: 5600,200-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Sandal et al. Serial No.: 09/426,340
Confirmation No: 1759 Group Art Unit: 1655
Filed: October 25, 1999 Examiner: Johannsen, D.
For: Method For Generating A Gene Library

AMENDMENT UNDER 37 C.F.R. 1.116

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Office Action mailed January 30, 2001, please amend the above-captioned application as follows (a marked up version pursuant to 37 C.F.R. 1.21 is attached hereto):

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IN THE CLAIMS:

Please substitute the following amended claims for the pending claims having the same claim numbers:

1. (Twice Amended) A method for generating a gene library from an environmental pool of organisms isolated from soil, animal dung, insect dung, insect gut, animal stomach, sea or lake water, waste water, sludge, or sediment, which gene library is enriched in DNA encoding a polypeptide with an activity of interest, which method comprises:

- a) subjecting the environmental pool of organisms to cultivation under conditions wherein the pool of organisms is enriched in organisms harbouring said DNA; and
- b) preparing a gene library directly from the enriched pool of organisms produced in said a).

2. (Twice Amended) The method of claim 1, wherein the conditions are culturing in a medium that contains a substrate for the gene product encoded by said DNA.

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13. (Twice Amended) The method of claim 1, wherein the gene library is enriched in DNA encoding an enzyme of interest.

21. (Twice Amended) A method of selecting a DNA sequence encoding a polypeptide of interest from an environmental pool of organisms isolated from soil, animal dung, insect dung, insect gut, animal stomach, sea or lake water, waste water, sludge, or sediment, which method comprises:

- a) subjecting the environmental pool of organisms to cultivation under conditions wherein the pool of organisms is enriched in organisms harbouring said DNA;
- b) producing gene libraries directly from the enriched pool of organisms produced in said a);
- c) screening the libraries of step b) for DNA encoding the polypeptide of interest; and
- d) selecting the DNA sequence of interest resulting from the screening of step c).

22. (Twice Amended) A method of claim 21, wherein the polypeptide of interest encodes an enzyme.

24. (Twice Amended) The method of claim 21, wherein the polypeptide of interest encodes one of a pectinase, amylase, galactanase, arabinase, xylanase or cellulase.

27. (Twice Amended) The gene library of claim 25, wherein the polypeptide is an enzyme which comprises a pectinase, an amylase, a galactanase, an arabinase, a xylanase or a cellulase.

REMARKS

Claims 1-19, 21-25 and 27 are pending in the application. Claims 2 and 13 have been amended to address a number of informalities. Claims 1 and 21 have been amended to specify that step b) entails "producing gene libraries directly from the enriched pool of organisms produced in" step a). Claims 21, 22 and 24 have been amended to replace the recitation "the desired gene" with the recitation "the polypeptide of interest" in order to address the rejection alleging lack of proper antecedent basis. Claim 27 has been amended to replace the recitation "DNA" with the recitation "polypeptide" in order to clarify that an enzyme is a polypeptide.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. Objections

Claims 2-4 and 13-16 are objected to for various informalities. In particular, claim 2 is objected to on the basis that the phrase "culturing in a medium contains a substrate" is incomplete, and that the phrase should recite, e.g., "culturing a medium that contains a substrate." Claim 13 is objected on the basis that the term "riched" should be amended to "enriched."

Applicants respectfully submit that these objections are rendered moot by the amendments to claims 2 and 13, which entail the amendments suggested by the Examiner.

II. The Rejection of Claims 21-24 under 35 U.S.C. 112

Claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite. The Examiner contends that the recitation "the desired gene" lacks proper antecedent basis.

Claim 21 has been amended to address the alleged indefiniteness. In particular, claim 21 now recites that step c) entails screening the libraries of step b) for DNA encoding the polypeptide of interest. Claims 22 and 24 have been amended in like manner.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. The Rejection of Claim 27 under 35 U.S.C. 112

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite. The Examiner contends that in the recitation of the phrase "wherein the DNA is an enzyme which comprises," is unclear because this phrase suggests that the "recited DNA is a protein."

Claim 27 has been amended to address the alleged indefiniteness by replacing the term "DNA" with the term "polypeptide."

For the foregoing reasons, Applicants submit that claim 27 overcomes this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. The Rejection of Claims 21-24 under 35 U.S.C. 112

Claims 21-24 are further rejected under 35 U.S.C. 112, second paragraph, for additional allegations of indefiniteness. In particular, the Examiner contends that, with respect to the recitation "method of selecting a DNA sequence of interest," it is unclear as to what is meant by "selecting a DNA sequence." The Examiner asks whether this language entails detection of a sequence, isolation of a molecule or a mental step of selecting a sequence. The Examiner also alleges that, with respect to step d) of claim 21, it is unclear how a "DNA sequence of interest" would "result from the screening of step c)." This rejection is respectfully traversed.

A proper indefiniteness rejection is applied to a recitation that fails to particularly point and distinctly claim the subject matter which an applicant regards as the invention. An indefiniteness rejection, however, is not properly asserted simply because a broad term is used in a claim. The latter principal applies to the rejections of claims 21-24, as previously summarized. Foremost, the phrase "selecting a DNA sequence" is defined in the specification as being "performed by standard methods in the art" and is plainly intended to further clarify the process that occurs after a library is screened. *See* the specification at page 8. In this regard, one of ordinary skill in the art would plainly understand how one could select a DNA encoding a polypeptide of interest in the context of the present invention, such as, by isolating or identifying a DNA sequence resulting from the process of screening a DNA library for DNA encoding the polypeptide of interest. Indeed, an example of how a DNA sequence of interest is selected from a screened DNA library is illustrated in the Examples section of the specification. *See, e.g.,* Example 5 (concluding that "These results demonstrate that it is possible to select a DNA sequence of interest with the present method of the invention.") However, because the step of "selecting a DNA sequence" can

be considered by an artisan to simply be part of the screening process, Applicants have consolidated step d) into step c).

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

V. The Rejection of the Claims under 35 U.S.C. 103

Claims 1-7, 13-19, 21-25 and 27 stand rejected under 35 U.S.C. 103 as allegedly being obvious over Duvick et al. in view of Sarkar and Upadhyay. Claims 1-9, 13-19, 21-25 and 27 stand rejected under 35 U.S.C. 103 as being obvious over Duvick et al. in view of Cotta. Claims 1-8, 10, 12-19, 21-25 and 27 stand rejected under 35 U.S.C. as being obvious over Duvick et al. in view of Jacobsen and Schlein. The substance of these rejections are set forth in the prior office actions. In response to Applicants' arguments, the Examiner contends that although Applicants argue that the instant invention avoids the time consuming and laborious intensive steps of isolating a positive strain prior to producing the library through several rounds of phenotype verification, that because the claims employ the transitional phrase "comprising", the claims are open to performing the time consuming and labor intensive steps. The 103 rejections are respectfully traversed.

In order to further clarify that the present invention avoids the need to perform time consuming and labor-intensive steps, Applicants have amended the claims to specify that the step of preparing a gene library involves preparing a gene library directly from the enriched pool of organisms produced in the preceding step. Duvick et al. plainly do not teach or suggest a method of preparing a gene library directly from an enriched pool of organisms. Further, as previously discussed, the secondary references do not teach or suggest modifying the Duvick et al. process to avoid the time consuming and labor intensive steps involved in preparing a DNA library according to the Duvick et al. method.

For the foregoing reasons, Applicants submit that the claims overcome the rejections under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of these rejections.

VI. Conclusion

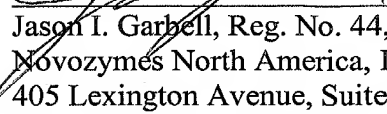
In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to

contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: June 26, 2001




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